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**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN JOSE**

LIFESCAN, INC. and
LIFESCAN SCOTLAND, LTD.,
Plaintiffs,

v.

SHASTA TECHNOLOGIES, LLC,
DECISION DIAGNOSTICS CORP.,
PHARMATECH SOLUTIONS, INC., and
CONDUCTIVE TECHNOLOGIES, INC.,
Defendants.

Case No. CV11-04494-EJD (PSG)

**REPLY IN SUPPORT OF LIFESCAN'S
MOTION FOR A PRELIMINARY
INJUNCTION (D.E. 176)**

Date: February 21, 2013
Time: 2:00 p.m.
Place: 5th Floor, Courtroom 4
Judge: Hon. Edward J. Davila

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6 21 U.S.C. § 360c(i)(1)(A)7

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1 **I. Introduction**

2 Defendants do not dispute that their GenStrip is a copy of the test strip of the '105
3 patent and that sales of the GenStrip will devastate LifeScan's business. Their effort to avoid an
4 injunction relies primarily on a baseless argument about patent exhaustion and an ill-conceived
5 validity challenge. The Court should reject their arguments and grant a preliminary injunction.

6 **Patent Exhaustion.** Defendants invite the Court to avoid "delving into" the merits of
7 the case by asserting the affirmative defense of patent exhaustion (D.E. 203 at 8-11). The
8 exhaustion doctrine, also known as the "first sale" doctrine, comes into play only where the patent
9 owner *sells* its patented product and earns the reward for its patented invention. The doctrine has no
10 application to the [REDACTED] of meters that LifeScan gives away free. For those meters, LifeScan receives
11 the reward on its patented invention later, on sales of disposable test strips used with the meters. The
12 exhaustion doctrine also is inapplicable to the remaining [REDACTED] of meters that LifeScan sells [REDACTED]
13 [REDACTED]. Those discounted sales do not permit LifeScan to earn its full reward and the meters do not
14 themselves embody the '105 patent, which also requires the use of test strips sold separately.

15 The remainder of the first twenty pages of Defendants' brief assumes the correctness
16 of their claim of patent exhaustion and attacks arguments LifeScan does not make. Defendants
17 argue irrelevantly that there is no contract barring patients' post-sale use of OneTouch Ultra meters
18 with the GenStrip and that, if there were, such a contract would violate the antitrust laws. D.E. 203
19 at 12-19. But LifeScan is asserting patent infringement, not breach of contract. Defendants
20 arguments might be of interest *if* the Court found patent exhaustion and *if* LifeScan then asserted that
21 it had a contract requiring meter owners to use LifeScan's own test strips. But that is not the case,
22 and the discussion is entirely irrelevant.

23 Turning to the merits, Defendants have little to offer.

24 **Infringement.** Defendants do not dispute that the GenStrip is a copy of the test strip
25 of the '105 patent. Defendants' Instructions for Use ("IFU") direct patients to use the GenStrip with
26 a LifeScan OneTouch Ultra meter, to perform the method of claim 3 of the '105 patent. Defendants
27

all but concede that a user following the IFU would directly infringe the '105 patent (their trumped-up defense is inconsistent with the IFU itself). And they do not dispute that, if that is so, they are guilty of inducing and contributing to that infringement. D.E. 203 at 19-21.

Validity. Defendants do not dispute that the invention of the '105 patent is novel, but claim – based on various combinations of ten different references – that it would have been obvious. D.E. 203 at 21-33. Defendants' scattershot attack is a scavenger hunt through the prior art, picking up ideas here and there that Defendants have stitched together to attempt to create the patented invention – by using the '105 patent itself used as a guide. This is impermissible hindsight. In fact, the references – most already considered by the Patent Office – identify problems, and teach solutions, that are very different from those of the '105 patent. The '105 patent solves three different problems with a single elegant solution unlike any other in the art. It is novel and not obvious, and Defendants have failed to demonstrate otherwise.

Irreparable harm. Defendants do not dispute that the GenStrip will cause significant lost sales and price erosion to LifeScan and they do not seriously dispute that they will be unable to make LifeScan whole for the resulting injury. D.E. 203 at 33-38. Absent an injunction, Defendants will have a free hand to destroy LifeScan's business without consequence.

II. Lifescan Has A Strong Likelihood Of Success On The Merits

A. LifeScan's Patent Rights Are Not Exhausted

Defendants rely on the doctrine of "patent exhaustion," also known as the "first sale" doctrine. The first sale doctrine comes into play "'when a patented device has been lawfully sold in the United States'" *Freescale Semiconductor, Inc. v. ChipMOS Techs.*, No. 5:09-CV-03689-EJD, 2013 U.S. Dist. LEXIS 10517, at *8 (N.D. Cal. Jan. 25, 2013) (citation omitted). Under the doctrine, "'an authorized sale of a patented product places that product beyond the reach of the patent.'" *Id.* (citation omitted). The first sale doctrine is an affirmative defense, and "the burden of proving patent exhaustion ... rests on the party that raises that defense." *Id.* at *9. On the facts of this case, Defendants cannot meet their burden of establishing patent exhaustion.

Defendants' exhaustion argument is that LifeScan's rights in the '105 patent are exhausted when LifeScan: (1) distributes Starter Kits that include a OneTouch Ultra meter and ten sample OneTouch Ultra test strips *free of charge* to patients suffering from diabetes; and (2) sells System Kits [REDACTED] that include a OneTouch Ultra meter, but no test strips. From 2008 through 2012, [REDACTED] of OneTouch Ultra meters were distributed free of charge in Starter Kits; the remaining [REDACTED] were distributed [REDACTED] in System Kits that do not contain any test strips. *See* Supp. Decl. of Peter Menziuso, ¶¶ 6-7. Both means of distribution reflect the core of LifeScan's business model: it distributes meters free of charge or [REDACTED] in order to earn the reward for its patent when users buy LifeScan's test strips for use in the meter, and thus practice the patented combination of a meter and a test strip. *See* D.E. 176 at 14; D.E. 189 (Menziuso Decl.) at ¶¶ 11-13.

1. LifeScan's Distribution of OneTouch Ultra Systems to Patients
Free of Charge Does Not Exhaust Its Patent Rights

For the [REDACTED] of the OneTouch Ultra meters that LifeScan distributes free of charge in Starter Kits, there is no patent exhaustion because there is no sale. Defendants' arguments would strip the first sale doctrine of the requirement that there be a *first sale*.

The Supreme Court summarized the applicable rule in *United States v. Masonite Corp.*, 316 U.S. 265 (1942): "The test has been *whether or not ... the patentee has received his reward for the use of the article*." *Id.* at 278 (emphasis added). This Court recently relied on *Masonite in Freescale Semiconductor*: "[T]he exhaustion of a patent depends on 'whether or not there has been such a disposition of the product that it may fairly be said that the patentee has received his reward for the use of the article.'" 2013 U.S. Dist. LEXIS 10517, at *8 (quoting *Masonite*, 316 U.S. at 278). *United States v. Univis Lens Co.*, 316 U.S. 241 (1942), is the same:

Our decisions have uniformly recognized that the purpose of the patent law is fulfilled with respect to any particular article *when the patentee has received his reward for the use of his invention by the sale of the article*

1 *Id.* at 251 (emphasis added). An unbroken line of Supreme Court cases supports this principle,¹
 2 which the Supreme Court reaffirmed most recently in *Quanta Computer, Inc. v. LG Electronics, Inc.*,
 3 553 U.S. 617 (2008): "Exhaustion is triggered only by a *sale* authorized by the patent holder." 553
 4 U.S. at 636 (emphasis added) (citing *Univis*, 316 U.S. at 249).

5 Defendants cite nothing to the contrary. Their only support for the proposition that
 6 the first sale doctrine under *patent law* does not require a sale is a case involving the *Copyright Act*,
 7 *UMG Recordings, Inc. v. Augusto*, 628 F.3d 1175, 1183 (9th Cir. 2011). But the Copyright Act has
 8 a provision, 17 U.S.C. § 109(a), with no counterpart in patent law, which provides that copyright
 9 exhaustion does not require a sale of the copyrighted article. There are "wide differences" on
 10 exhaustion between patent law and copyright law such that "the cases which relate to the one subject
 11 are not controlling as to the other." *Bobbs-Merrill Co. v. Straus*, 210 U.S. 330, 345-46 (1908)
 12 (citation omitted); *see also Denbicare U.S.A., Inc. v. Toys "R" Us, Inc.*, 84 F.3d 1143, 1151 (9th Cir.
 13 1996) (rejecting an argument that the "trademark law's 'first sale' doctrine should be made to
 14 conform to patent law, rather than to copyright law").

15 The two patent cases Defendants cite both involve *sales*. In *TransCore, LP v. Elec.*
 16 *Transaction Consultants Corp.*, 563 F.3d 1271 (Fed. Cir. 2009), the parties had entered into a
 17 settlement agreement, supported by consideration, and the Federal Circuit concluded that the
 18 plaintiff was legally estopped from asserting a later-issued patent in order for the defendant "to

19
 20 ¹ *See, e.g., Keeler v. Standard Folding Bed Co.*, 157 U.S. 659, 661 (1895) (where a patented product
 21 is "sold ... for a satisfactory compensation ... all the rights secured to [the patentee] by [the] letters
 22 patent ... go to the purchaser for a valuable consideration, discharged of all the rights of the patentee
 23 previously attached to it" (internal quotation omitted)); *Bloomer v. Millinger*, 68 U.S. 340, 350
 24 (1864) (patent exhaustion applies where "consideration has been paid to [the patentee] for the right
 25 [to make, use or sell the invention]" by a buyer who "purchased the right to [do so]"); *Mitchell v.*
 26 *Hawley*, 83 U.S. (16 Wall.) 544, 546-47 (1873) (when "consideration has been paid to [the patentee]
 27 for the thing patented, the rule is well established that the patentee must be understood to have parted
 28 to that extent with all of his exclusive right, and that he ceases to have any interest whatever in the
 patented machine"); *Bloomer v. McQuewan*, 55 U.S. 539, 553-54 (1852) (stating that an invention is
 outside the patent monopoly when an inventor "lawfully sell[s]" it to "a purchaser" and rejecting
 assertion that a patentee's rights to an invention continue after a sale "for a valuable and fair
 consideration").

1 obtain the benefit of its bargain" *Id.* at 1279. *Static Control Components, Inc. v. Lexmark Int'l,*
 2 *Inc.*, 615 F. Supp. 2d 575 (E.D. Ky. 2009), involved the "sale of . . . patented items," *id.* at 586.
 3 Addressing the seller's reduced price, not free distribution, it offers an untenable theory that *Quanta*
 4 overruled an unbroken line of Supreme Court cases *sub silentio* and made the seller's reward
 5 irrelevant. *Static Control* has not been followed on this proposition by any court and its reasoning is
 6 inconsistent with *Quanta's* reaffirmation that "[e]xhaustion is triggered only by a *sale* authorized by
 7 the patent holder." *Quanta*, 553 U.S. at 636 (emphasis added) (citing *Univis*, 316 U.S. at 249).

8 For the [REDACTED] of OneTouch Ultra meters that LifeScan gives away to patients in the
 9 expectation of profiting later, Defendants cannot prove the affirmative defense of patent exhaustion.

10 **2. LifeScan's Patent Rights Are Not Exhausted for the Remaining**
 11 **[REDACTED] of Meters That It Sells Separate From Any Test Strips**

12 LifeScan sells the remaining [REDACTED] of its OneTouch Ultra meters [REDACTED] in System
 13 Kits that do not include any test strips. *See Menziuso Supp. Decl.*, ¶ 7. That is significant because
 14 claim 3 of the '105 patent requires *both* (1) a "disposable test strip" with a particular configuration of
 15 sensors, and (2) a device (*e.g.*, a meter) capable of comparing the current in the sensors. As a result,
 16 the distribution of meters alone is insufficient to allow anyone to practice claim 3 and presumptively
 17 does not, and cannot, exhaust the patent.

18 The exhaustion doctrine strikes a balance between the patent owner's right to profit
 19 from its invention *before* exhaustion and the customer's right to use goods without restriction *after*
 20 exhaustion. In two cases, *Quanta* and *Univis*, the Supreme Court has assessed that balance where
 21 the patent owner distributed less than the complete patented item and thus presumptively had not
 22 exhausted the patent. The balance struck by the Court protects the patent owner unless the product it
 23 has sold "substantially embodies the patent." *Quanta*, 553 U.S. at 638. In this analysis, the Court
 24 considers whether: (1) the component that was sold "all but completely practice[s] the patent";
 25 (2) there are other "reasonable and intended use[s]" of that component; and (3) the patent owner has
 26

1 already "demanded and received" in the purchase price the "reward" for both "the article and the
2 invention which it embodies." *Quanta*, 553 U.S. at 631, 633; *Univis*, 316 U.S. at 251.²

3 Defendants' response misrepresents both the holding in *Quanta* and the facts of this
4 case. Defendants fail all three of these tests and are unlikely to prevail on the affirmative defense of
5 exhaustion with respect to the [REDACTED] of meters that LifeScan sells [REDACTED]

6 **a. The Meters Do Not Embody the Invention of the '105 Patent.**

7 On the law, Defendants fail to recognize that *Quanta's* holding was narrow. *Quanta*
8 makes clear that the sale of one component of a patented combination ordinarily does not constitute
9 exhaustion. It upheld the affirmative defense of exhaustion because it found that Intel's chips
10 "substantially embodie[d] the patent." *Quanta*, 553 U.S. at 638. Thus, the Court found it material
11 that Intel's chips "included all the inventive aspects of the patented methods," "all but completely
12 practice[d] the patent," and "had no reasonable noninfringing use," while the remaining components
13 were "standard." *Id.* at 633, 638. Similarly, the Court noted that the lens blanks in *Univis* were "not
14 central to the patents," "not included in any detail in the patent," and "incidental to the invention."
15 *Id.* at 633. Defendants' burden to show exhaustion is a heavy one.

16 On the facts, Defendants significantly understate the importance of the test strips to
17 the patented method of the '105 patent. The '105 patent devotes most of its text to describing the
18 unique design of its test strip and how that design solves three different problems in the disposable
19 test strip art. This is described more fully below (at pages 13-14) and in Dr. Meyerhoff's
20 Declarations. D.E. 176-2 at ¶¶ 9-25; Meyerhoff Supp. Decl. ¶¶ 39-50. Thus, unlike the patents in
21 *Univis*, the '105 patent addresses the test strips "in detail" and does not treat them as "incidental" to
22 the claimed method. *Quanta*, 553 U.S. at 633. Figures 1-7 of the '105 patent depict the test strips;
23 none of the figures illustrates the meters. The test strips are thus anything but "standard

24
25 ² In *Quanta*, the Supreme Court did not address whether the patent owner had received its "reward"
26 and the briefs indicate that the record contained no evidence on that issue. The issue was raised in
27 *Univis*, whose reasoning the *Quanta* Court adopted. See *Quanta*, 553 U.S. at 631-34; *Univis*, 316
28 U.S. at 251-52.

1 components." *Id.* They embody key aspects of the invention and are usable only with LifeScan's
 2 meters. If anything, it is the meters, and not the strips, that are "not included in detail" in the patent
 3 and treated as "incidental to the invention." *Id.* The meters perform relatively simple programming
 4 steps of the claimed methods. Unlike the Intel chips, the LifeScan meters do not permit anyone to
 5 practice the '105 patent merely by "the addition of standard parts." *Id.* at 634. It is only when the
 6 meters are used in combination with the novel test strip of the '105 patent that all of the steps of the
 7 claimed methods can be performed. *See* D.E. 176-2 (Meyerhoff Decl.), ¶¶ 43-48.

8 **b. The Meters Have Reasonable Non-infringing Uses.**

9 The exhaustion doctrine also is inapplicable because the meters have "reasonable
 10 noninfringing use[s]." *Quanta*, 553 U.S. at 638. As described in Dr. Meyerhoff's previous
 11 declaration, *see* D.E. 176-2, ¶¶ 43-48, Defendants could have designed non-infringing test strips that
 12 would work with LifeScan's meters, but they chose not to do so. Notably, Defendants' expert does
 13 not disagree. Defendants have no credible excuse for their failure to design such a strip and that
 14 failure is fatal to their affirmative defense of exhaustion.

15 In response, Defendants assert that no commercial test strip currently uses the
 16 alternatives Dr. Meyerhoff identified. D.E. 203 at 11. Of course, that is true only because
 17 Defendants chose not to create such an alternative. In any event, "reasonable noninfringing uses" are
 18 not limited to uses that are commercially available. Hypothetical or possible uses qualify, even if
 19 they would have been unwise from a business perspective. *Glass Equip. Dev., Inc. v. Besten, Inc.*,
 20 174 F.3d 1337, 1343 (Fed. Cir. 1999) ("[A] legally acceptable noninfringing use need not be as
 21 profitable as the patented method – it need only be reasonable.").

22 Defendants further argue that "the FDA would not approve such a [noninfringing]
 23 strip to work with any OneTouch Ultra meter." D.E. 203 at 11. Defendants have not submitted any
 24 evidence to support this proposition and there is no basis for it. Although Defendants chose to copy
 25 the patented design of the test strip claimed in the '105 patent, FDA approval did not require the
 26 creation of an identical test strip, but only one that produces substantially equivalent results. *See* 21

1 U.S.C. § 360c(i)(1)(A). In fact, in other respects (not relevant to the '105 patent), the GenStrip
2 differs from OneTouch Ultra test strips (*e.g.*, it is made of different materials).

3 It is no answer for Defendants to say that they preferred to copy LifeScan's patented
4 design, instead of using other reasonable test strip designs that would work with LifeScan's meters.
5 Because the LifeScan meters can reasonably be used with non-infringing test strips – which
6 Defendants could have designed and used without infringing the '105 patent – Defendants cannot
7 now claim that the sale of meters alone exhausts LifeScan's patent rights. *Quanta*, 553 U.S. at 638.

8 **c. LifeScan has not received the reward for its invention.**

9 For the [REDACTED] of OneTouch Ultra meters that are sold in System Kits, Defendants'
10 exhaustion argument also fails because LifeScan sells these meters [REDACTED] without receiving the
11 "reward" for its invention. *Univis*, 316 U.S. at 251; *Masonite*, 316 U.S. at 278. That reward comes
12 from the sale, over time, of test strips for use in the meter. For the meters LifeScan gives away
13 without charge and those it sells [REDACTED] LifeScan relies on its patent rights to enable it to obtain
14 a reward for its invention by selling the novel test strips necessary to practice the patented invention.

15 **B. Defendants' Contract and Antitrust Arguments Are Irrelevant**

16 Defendants devote much of their brief to rebutting arguments that LifeScan does not
17 make and that assume their exhaustion arguments are correct. They contend that *if* the '105 patent is
18 exhausted, LifeScan could not establish that it has a contract with its customers requiring them, as a
19 "post-sale condition," to use LifeScan test strips and, further, that *if* such a contract existed it would
20 be an illegal tying agreement. D.E. 203 at 11-19. Let us be clear. LifeScan does not contend that
21 there is any contract barring patients from using OneTouch Ultra meters with other companies' test
22 strips. This is a patent infringement case, not a contract case. LifeScan is accusing Defendants of
23 inducing infringement and contributory infringement, not of interfering with a supposed contract
24 between LifeScan and the users of its meters. The *Quanta* Court reserved decision on the
25 enforceability of such a contract, but this case presents no reason to address that issue. *See Quanta*,

1 553 U.S. at 637 n.7 ("[W]e express no opinion on whether contract damages might be available even
2 though exhaustion operates to eliminate patent damages.").

3 Likewise, because LifeScan does not rely on a contract imposing supposed "post-sale
4 conditions" on its users, the antitrust issues that Defendants raise at every turn in the bend (*e.g.*, D.E.
5 203 at 1, 12-19; D.E. 160 at 8) are completely irrelevant. Thus, there is no reason to wade into why
6 *Motion Picture Patents Co. v. Universal Film Mfg. Co.*, 243 U.S. 502 (1917), is inapposite. (It
7 relates to tying the sale of a patented item to an unpatented item and has been "substantially
8 undermined" by Congress' enactment in 1988 of amendments to Section 271(d) of the patent statute,
9 35 U.S.C. § 271(d), while the Supreme Court's 1917 disapproval of tying arrangements has
10 "substantially diminished" over time. *Illinois Tool Works, Inc. v. Indep. Ink, Inc.*, 547 U.S. 28, 31,
11 35 (2006).). Nor need we address Defendants' implausible assertion that LifeScan – whose prices
12 are falling, *see* Menziuso Supp. Decl., ¶¶ 11-13 – "has sufficient power to raise price or impose
13 onerous terms 'that could not be expected in a completely competitive market.'" D.E. 203 at 17
14 (quoting *Moore v. Jas. H. Matthews & Co.*, 550 F.2d 1207, 1215 (9th Cir. 1977)). To the extent the
15 Court is interested in these issues, they are more fully addressed in LifeScan's response to
16 Defendants' motion to dismiss based on *Quanta*. D.E. 208 at 5-10.

17 LifeScan's case is straightforward and does not depend on any claim of contract
18 rights. LifeScan relies on its '105 patent. LifeScan's rights in that patent have not been exhausted
19 either by its free distribution or [REDACTED] sales of meters. As a result, under the patent laws,
20 LifeScan retains its unfettered right as the owner of the '105 patent – subject to any implied license
21 (discussed below) – to dictate how its patented invention may be made, used or sold, on pain of a
22 charge of infringement. *See* 35 U.S.C. § 271(a) ("[W]hoever without authority makes, uses, offers to
23 sell, or sells any patented invention, within the United States . . . , infringes the patent."). By
24 inducing others to use LifeScan's invention without permission, Defendants are guilty of
25 contributory infringement and inducing infringement.

1 **C. Defendants Do Not Assert an Implied License Defense**

2 Where, as here, a patent has not been exhausted, the patentee may nonetheless have
3 constrained its rights by granting a third party an implied use license. Here, LifeScan grants the
4 users of its meters an implied license to use its meters with LifeScan test strips. That license is set
5 forth clearly in packaging of LifeScan's products, D.E. 189, Ex. B:

6 Use of the monitoring device included here is protected under one or
7 more of the following U.S. patents: 7,250,105 Purchase of this
8 device does not act to grant a use license under these patents. Such a
9 license is granted only when the device is used with OneTouch Ultra
10 test strips.

11 The last sentence of this legal notice unequivocally grants a use license to meter
12 owners to use their meters with LifeScan's test strips, and as a result, LifeScan has surrendered its
13 rights under the patent laws to interfere with such use. Contract or not, LifeScan meter owners
14 would be able to establish the affirmative defense of implied license if LifeScan attempted to accuse
15 them of infringement when they use LifeScan test strips with their meters.

16 Defendants have no such defense, and have opted not to raise one here. They did
17 raise an implied license theory earlier, when they opposed LifeScan's motion for leave to amend to
18 add the '105 patent. D.E. 160 at 7-8. Defendants have not repeated that defense on this motion,
19 undoubtedly recognizing that an implied license defense has prevailed in "relatively few" cases.
20 *Bandag, Inc. v. Al Bolser's Tire Stores, Inc.*, 750 F.2d 903, 925 (Fed. Cir. 1984). "As the alleged
21 infringers, [Defendants would] have the burden of establishing the existence of an implied license as
22 an affirmative defense." *Carborundum Co. v. Molten Metal Equip. Innovs.*, 72 F.3d 872, 878 (Fed.
23 Cir. 1995). As part of that burden, Defendants would have to show what they cannot – that "the
24 purchased device has no noninfringing uses." *Glass Equip*, 174 F.3d at 1343; *see also Bandag*, 750
25 F.2d at 925.

26 Further, as this Court has explained, "the defense[] of [implied] license requires a
27 showing of '[a]ny language used by the owner of the patent, or conduct used on his part exhibited to
28 another from which that other may properly infer that the owner consents'" to the implied license

that is asserted. *Freestyle Semiconductor*, 2013 U.S. Dist. LEXIS 10517, at *9. An "implied license" defense can only prevail if "the circumstances of the sale ... 'plainly indicate that the grant of a license should be inferred.'" *Met-Coil Sys. Corp. v. Korners Unlimited, Inc.*, 803 F.2d 684, 686 (Fed. Cir. 1986) (emphasis added) (citation omitted). Here, the circumstances of the sale do not "plainly indicate" anything of the sort. The notice on the packaging for LifeScan's OneTouch Ultra meters states, *inter alia*, that a use license under the '105 patent "is granted only when the [meter] is used with [LifeScan's] OneTouch® Ultra® Test strips." D.E. 189, Ex. B. This Court relied on LifeScan's notice in rejecting the "implied license" argument when Defendants raised it earlier, in arguing that this case was futile. D.E. 169 at 6. The Court concluded that Defendants "have not proven that Plaintiffs' warning does not preclude the finding of an implied license." *Id.*³

The combination of LifeScan's notice, the availability of non-infringing alternatives (which Defendants opted not to create) and the fact that LifeScan gives the meter away or sells it makes it impossible for Defendants to carry the affirmative burden of proving an implied license. In any event, by failing to raise the implied license defense in response to LifeScan's motion for a preliminary injunction, Defendants have waived the issue, at least for now.

D. Defendants Infringe the '105 Patent

1. Users of the GenStrip Will Directly Infringe the '105 Patent

For LifeScan to prevail on its claims of inducing and contributory infringement, there must be direct infringement. In its prior submissions, LifeScan demonstrated that using the copycat GenStrip with OneTouch Ultra meters meets every limitation of claim 3 of the '105 patent and infringes that claim. *See* D.E. 176-2, ¶¶ 27-41. Defendants have little to say in response.

³ *See LifeScan Inc. v. Polymer Tech. Int'l Corp.*, No. C94-672R, 1995 U.S. Dist. LEXIS 4916, at *45 (W.D. Wash. Jan. 3, 1995) (The notice on the packaging for LifeScan's meters "*preclud[es] a finding of implied license.*") (emphasis added); *LifeScan, Inc. v. Can-Am Care Corp.*, 859 F. Supp. 392, 395 (N.D. Cal. 1994) (The court "cannot determine that, as a matter of law, the license restriction [on the packaging of LifeScan's monitors] is insufficient" to negate an implied license to use the monitors with other company's test strips.).

Defendants' only argument is that use of the GenStrip does not meet the claim limitation that requires "measuring an electric current at each working sensor part proportional to the concentration of said substance [glucose] in the sample liquid [blood]...." *See* D.E. 203 at 19-20. According to Defendants, this claim limitation cannot be met by any "known device" because "[t]he science set forth in the claims of the '105 Patent" supposedly is "incorrect." *Id.* at 33. But as the '105 patent explains, "known glucose measuring devices" in the prior art provided the same "proportional" measurement of glucose required by the claim. D.E. 170-3 at col. 1:26-38. Defendants concede this in arguing that Winarta '229 "would *necessarily* 'measure an electric current ... *proportional* to the concentration" of glucose (subject, of course, to their inconsistent argument that such a scientific relationship "is simply incorrect"). D.E. 203 at 23 (*italics added*).

The GenStrip's FDA-approved IFU – which Defendants place in every GenStrip package – eliminates this defense. In their IFU, Defendants admit that the GenStrip uses the same relevant "principal [*sic*]" as the disputed claim limitation: "Glucose in blood combines with an enzyme in the [GenStrip]. *This produces an electric current in the Meter in proportion to the glucose level.*" Meyerhoff Supp. Decl., Ex. 2 at PHARM0005237 (*emphasis added*). Having admitted this to the FDA, Defendants cannot seriously argue the opposite here. *See id.*, ¶¶ 160-65.

2. Defendants Have No Response to the Charges of Inducing and Contributory Infringement

With the conclusion that use of the GenStrip with a LifeScan meter directly infringes the '105 patent, infringement is proved. Defendants offer no response to LifeScan's showing that, if there is direct infringement, they are guilty of inducing and contributory infringement.

E. The '105 Patent Is Not Invalid

The only remaining issue on likely success is patent validity. When courts address validity in the preliminary injunction context, they "'view[] the matter in light of the burdens and presumptions that will inhere at trial," *Astrazeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1050 (Fed. Cir. 2010) (citation omitted), which include the presumption of validity and Defendants' burden of

1 overcoming that presumption with clear and convincing evidence. The party seeking a preliminary
 2 injunction makes a sufficient showing if it demonstrates that the patent is "likely to withstand the
 3 [defendant's] validity challenge" *Id.* at 1054. The '105 patent is more than "likely to withstand"
 4 the strained arguments Defendants offer here.

5 **1. The Claimed Invention Would Not Have Been Obvious**

6 Defendants rely on ten prior art references, which they mix and match in various
 7 combinations to create eighteen "Obviousness Grounds." D.E. 203 at 23-33. The common thread is
 8 that all of their "Obviousness Grounds" rely upon either Winarta '229 or Nankai '420 as a primary
 9 reference. Neither Winarta nor Nankai renders the claimed invention obvious, alone or in
 10 combination with the many other references Defendants rely upon. *Hybritech, Inc. v. Monoclonal*
 11 *Antibodies, Inc.*, 802 F.2d 1367, 1383 (Fed. Cir. 1986) ("The large number of references, as a whole,
 12 relied upon by the district court to show obviousness, about twenty in number, skirt all around but do
 13 not as a whole suggest the claimed invention, which they must, to overcome the presumed
 14 validity."); *Endress + Hauser, Inc. v. Hawk Measurement Sys. Pty.*, 892 F. Supp. 1107, 1121 (S.D.
 15 Ind. 1995) ("An infringer's need to cite a large number of prior art references can indicate to a court
 16 that the invention was novel and not obvious."); *Corometrics Medical Systems, Inc. v. Berkeley Bio-*
 17 *Engineering, Inc.*, No. 75-203, 1977 U.S. Dist. LEXIS 17126, at *23-24 (N.D. Cal. 1977) (same).

18 Defendants' obviousness theories have multiple defects. Defendants rely on
 19 references that the PTO considered and rejected in allowing the '105 patent, plus other references
 20 that are cumulative of information the PTO considered; they ignore the differences between the
 21 patented invention and the solutions their references suggest; they rely on hindsight; they fail to
 22 identify any reason why a person of ordinary skill in the art would have combined their cited
 23 references; and they ignore secondary considerations of nonobviousness.

24 **a. The '105 Patent Offers a Novel Solution to Problems of Reliability**

25 Unlike anything in the prior art, the '105 patent identifies and solves three related
 26 problems involving disposable test strips in one elegant design. As the patent explains, test strips

1 can give inaccurate results if their sensors are not fully covered by blood, D.E. 170-3 at col. 1:39-
 2 41, or if the sensors have defects arising from the production process or from accidental damage by a
 3 user. *Id.* at col. 1:55-60. Meanwhile, the amount of blood used in the test is small – one drop – and
 4 it is desirable to use all of the blood sample in the measurement to increase the precision of the
 5 results. *Id.* at col. 4:7-13. Addressing all three of these problems in one design – which Defendants
 6 have copied – LifeScan's inventors created a unique test strip in which the working sensor is divided
 7 into two parts, instead of using one larger working sensor, as taught in the prior art. Blood is
 8 required to flow sequentially over both sensor parts. Measurements from both sensors parts are then
 9 compared. If the results from both sensor parts are not comparable, an error reading is given. In that
 10 event, the test strip can be discarded because the strips are designed to be inexpensive and
 11 disposable. On the other hand, if there is no error reading, the data from both substantially identical
 12 working sensor parts can be combined, increasing the precision of the results with a minimum
 13 amount of blood. The patented invention thus features a disposable test strip arranged so that for
 14 "[1] a given minimum sample volume, detection of [2] inadequate fill and of [3] defects in the
 15 working sensor part is provided by separating the area of the working sensor part into two." *Id.* at
 16 col. 2:53-56 (bracketed numbers added).

17 The result is an innovative measurement system – test strip plus meter – that has
 18 substantially greater reliability than prior art systems, without requiring a larger sample of blood.
 19 Defendants concede the novelty of the invention by not raising an anticipation defense. Their
 20 obviousness challenge is strained and without merit.

21 **b. Defendants Improperly Use Hindsight**

22 The Supreme Court has warned against using hindsight in analyzing obviousness.
 23 *Graham v. John Deere Co.*, 383 U.S. 1, 36 (1966). Instead of heeding that warning, Defendants
 24 conduct a scavenger hunt through the prior art with the '105 patent firmly in mind. They pluck ideas
 25 from disparate references in an effort to reconstruct the invention. Even then, the resulting
 26

1 combinations that Defendants create do not have all features of the claimed invention without still
2 further modifications that Defendants cannot find in *any* prior art reference.

3 Defendants' expert Dr. Wang does *not* start with the problems that the prior art
4 recognized and then address the solutions that would have been obvious at the time. Instead, he
5 addresses questions that would not arise without hindsight knowledge of the invention. For
6 example, much of his analysis begins with the premise that "the test strip of Winarta ('229) is
7 *capable* of taking multiple measurements," *e.g.*, at D.E. 206 at ¶ 35 (emphasis added). Yet he does
8 not note that Winarta would require significant design modifications – which it does not advocate
9 and which are contrary to its teaching – before it would actually be "capable" of the multiple
10 measurements described by the '105 patent. Nor does he address whether Winarta identifies the
11 three problems that motivated the '105 inventors (it does not) or whether Winarta suggests the
12 solution claimed by the inventors (it does not). Dr. Wang's reliance on Winarta begins by examining
13 the design of the '105 patent and working backwards. *See* Meyerhoff Supp. Decl., ¶¶ 84-95.

14 This stands the obviousness inquiry on its head. The appropriate question is whether
15 the patented invention would have been obvious to a person of ordinary skill in the art who was
16 *unaware* of the patented invention – *not* whether a skilled person who was told about the patented
17 invention would have found obvious ways to replicate it. After posing an incorrect question,
18 Defendants use hindsight in addressing it. They rely on references "selectively culled from the prior
19 art" with the benefit of hindsight to try to re-construct the claimed invention. *Star Scientific, Inc. v.*
20 *R.J. Reynolds, Tobacco Co.*, 655 F.3d 1364, 1375 (Fed. Cir. 2011) (citation omitted). This is not a
21 proper foundation for an obviousness analysis.

22 In hindsight, the '105 patent has an appealing simplicity. But that is actually
23 compelling proof of its novelty. "[S]implicity, particularly in an old and crowded art, may argue for
24 rather than against patentability." *Outside the Box Innovations, LLC v. Travel Caddy, Inc.*, 695 F.3d
25 1285, 1298 (Fed. Cir. 2012) (citation omitted); *accord* *Sensonics, Inc. v. Aerosonic Corp.*, 81 F.3d

1 1566, 1570 (Fed. Cir. 1996) ("[S]implicity does not establish obviousness; indeed, simplicity may
2 represent a significant and unobvious advance over the complexity of prior devices.").

3 **c. Defendants Improperly Rely on Winarta and Nankai**

4 Defendants' eighteen "Obviousness Grounds" all rely on either Winarta '229 or
5 Nankai '420, in combination with other references that Defendants selected in an effort to re-
6 construct the invention. Defendants claim that these two references, in and of themselves, disclose
7 the test strip of the '105 patent or render it obvious, citing a preliminary statement the Patent
8 Examiner made in reviewing another patent application. In fact, Winarta '229 addresses only one of
9 the three problems identified in the '105 patent – and then solves that single problem in an entirely
10 different way with a different test strip. Nankai does not address any of the three problems and,
11 again, it uses a different test strip. Meanwhile, Defendants' reliance on the Examiner's comments in
12 connection with a different application is misplaced.

13 **Winarta '229.** The Examiner was aware of Winarta when he allowed the '105 patent.
14 Winarta's solution to the problem of inadequate sample volume in a disposable test strip is very
15 different from that of the patented invention. While the patented invention measures glucose at two
16 working sensors, Winarta takes measurements at only one working electrode (W). Winarta uses a
17 pseudo-working electrode (Wo) as a "trigger" to indicate when blood has reached beyond the
18 working electrode (W) – *not* to measure glucose. Because Winarta does not take multiple
19 measurements, Dr. Wang is relegated to arguing that it is "capable" of doing so. As he implicitly
20 concedes, Winarta never actually uses two sensors to measure glucose. As a result, it does not
21 compare glucose measurements at two sensors or provide an error message based on such a
22 comparison. Moreover, Winarta's pseudo-working electrode (Wo) is smaller than the working
23 electrode. If anything, one of skill would have been motivated to make it even smaller (rather than
24 the same size as the working electrode) because Winarta is concerned with very small blood
25 samples. *See* Meyerhoff Supp. Decl., ¶¶ 58-67, 107.

Winarta describes this "trigger" approach as a satisfactory solution to the problem of inadequate blood fill. Thus, it provides no reason to seek another solution. The inventors of the '105 patent noted the "trigger" solution, D.E. 170-3 at 2:39-48, but recognized that that approach had its own drawbacks. It does not determine whether the working electrode is completely covered with blood, rather than covered to some extent. Use of a "trigger" also wastes valuable "real estate" on a small test strip, uses blood without measuring its glucose level, and provides no protection against defects in the electrode. The claimed invention solves those problems; Winarta leaves them unidentified and unsolved. *See* Meyerhoff Supp. Decl., ¶¶ 58-67, 107.

Nankai '410. The Examiner reviewed Nankai in allowing the '105 patent. Nankai generally addresses the problem of accuracy in measurement, without identifying or addressing the problems identified and solved by the '105 patent. Nankai relies on measurements of multiple sensors and averages the results. In this way, Nankai believed precision could be increased by reducing the variability of any particular measurement. Nankai does not identify either defective sensors or inadequate blood volume as reasons for variability in measurement and the averaging technique is not a solution to those problems – in such cases, it would simply mix good data with bad. Moreover, like all prior art averaging techniques, Nankai would suggest adding electrodes to improve accuracy, rather than recognizing the benefit, in a disposable test strip, of minimizing the number of sensors by dividing one sensor into two parts, as in the '105 patent.

Because Nankai did not identify either the problems or the solutions addressed in the '105 patent, Nankai's disposable strip had an entirely different design. Rather than placing the sensor parts downstream of one another, Nankai teaches working electrodes arranged parallel to each other, so that blood flows across them simultaneously. That arrangement would not suggest arranging sensors sequentially downstream of each other, so that blood will reach the second sensor part only after it covers the first sensor part. *See* Meyerhoff Supp. Decl., ¶¶ 68-75, 82-83.

The Rejection of the '714 Application is Irrelevant. Defendants place great weight on the fact that, during an initial review of a different patent application, the Examiner issued an

1 initial office action rejecting the test strip over Winarta '229 and Nankai '410, both of which he had
 2 previously examined. Based on this, Defendants assert that there is "a cloud over the '105 Patent."
 3 D.E. 203 at 22. This is ludicrous. The same Examiner had just approved the '105 patent! The '714
 4 application was filed as a continuation of the '105 patent and, upon initial review of the claims, the
 5 Examiner did issue a non-final rejection. This is utterly routine. Examiners receive administrative
 6 credit for issuing initial rejections and almost invariably issue them.⁴ For reasons not reflected in the
 7 record, LifeScan did not respond and it never prosecuted the application.

8 LifeScan's failure to pursue the '714 application says nothing about the merits of the
 9 Examiner's initial analysis or the patentability of the '105 patent. As befits an initial office action,
 10 the Examiner's comments were tentative; indeed, he expressly invited "a contrary showing." D.E.
 11 207-3 at 19. Moreover, his tentative observations are incorrect. *See* Meyerhoff Supp. Decl., ¶¶ 76-
 12 83. In any event, whatever bearing the Examiner's initial comments may have on the test strip that
 13 was part of the '714 application, they have no bearing on the patented method for using the test strip
 14 and meter claimed in the '105 patent.

15 **d. Defendants' Additional References Add Nothing**

16 The other references that Defendants combine with Winarta '229 and Nankai '410 do
 17 not add anything meaningful to the mix. By and large, they all involve standard measurement
 18 techniques, such as averaging, that would be known in any event to one of skill in the art. They do
 19 not identify the three problems addressed in the '105 patent, let alone provide any motivation to
 20 solve them in one novel design. All are addressed in Dr. Meyerhoff's Supplemental Declaration (at
 21 ¶¶ 84-135). The most germane are addressed below.

22
 23 ⁴ *See, e.g.,* R. Polk Wagner, *Reconsidering Estoppel: Patent Administration and the Failure of*
 24 *Festo*, 151 U. Pa. L. Rev. 159, 221 (2002) ("[E]xaminers are given administrative 'credit' for
 25 imposing initial rejections, and then allowing the patent to issue."); Mark A. Lemley & Bhaven
 26 Sampat, *Examining Patent Examination*, 2010 Stan. Tech. L. Rev. 2, 7 (2010) ("Overwhelmingly,
 the first reaction a patent examiner has to an application is a non-final rejection. 86.5% of the PTO's
 first office actions were non-final rejections.").

1 **Say '752, Horii '998, and Schulman '344** do not even deal with disposable test
 2 strips. Rather, they address non-analogous technology, *i.e.*, sensors that do continuous
 3 measurements over time. Horii '998 does not even involve blood measurements. Say '752 and
 4 Schulman '344 involve sensors that are implanted beneath the skin to take continuous measurements
 5 over an extended period of time. Such non-analogous art is of little or no relevance. *In re Klein*,
 6 647 F.3d 1343, 1351-52 (Fed. Cir. 2011); *In Re Clay*, 966 F.2d 656, 659-60 (Fed. Cir. 1992).

7 With implantable sensors, there is no problem of inadequate blood fill because the
 8 sensor is in the body and in constant contact with blood. There is no problem of manufacturing
 9 defects because the sensors are reuseable and can be tested prior to use. And there is no problem of
 10 minimizing the size of the working sensor. This art is not concerned with, and not does not identify,
 11 any of the problems addressed in the '105 patent, let alone the solution. Defendants note that these
 12 patents use averaging and comparisons to test whether an implantable sensor has degraded
 13 sufficiently over time so as to need to be replaced. There is nothing novel about these teachings
 14 (references to averaging also appear in Yee '256), nor anything relevant to the disposable art. *See*
 15 Meyerhoff Supp. Decl., ¶¶ 16-19, 109-21.

16 **The Khazanie and Lichten textbooks:** These are mathematics textbooks. They do
 17 not mention glucose test strips. Defendants rely on these textbooks for the unremarkable proposition
 18 that one can determine a "mean deviation" or a "standard deviation" or an "average deviation" when
 19 averaging numbers. *See* D.E. 206 at ¶¶ 52, 56-57, 81. Such knowledge is background noise to one
 20 of skill in the art, but does nothing to suggest either the problems or the solution of the '105 patent.
 21 *See* Meyerhoff Supp. Decl., ¶¶ 125-26.

22 Looking at all of Defendants' combinations as a whole, they do not provide *any*
 23 reason why a person of ordinary skill – unaware of the '105 patent – would try to create the patented
 24 combination. To the contrary, to the extent the prior art addresses problems even tangentially related
 25 to those addressed by the '105 patent, the prior art is satisfied with its (inferior) solutions. It does
 26 not identify any remaining problems or suggest the need for any new solutions. *See In re Nomiya*,

509 F.2d 566, 572 (C.C.P.A. 1975) ("If... there is no evidence ... that a person of ordinary skill ... would have expected the problem ... to exist at all, it is not proper to conclude that the invention which solves this problem ... would have been obvious to that hypothetical person of ordinary skill"). Without the benefit of hindsight, one of ordinary skill would have had no reason to combine the prior art as Defendants suggest, to make the '105 patent. *See* Meyerhoff Supp. Decl., ¶¶ 118-29.

**e. The PTO Considered Defendants' References and References
With the Same Teachings, and Rejected Defendants' Arguments**

"[A] party challenging validity shoulders an enhanced burden if the invalidity argument relies on the same prior art considered during examination by the U.S. Patent and Trademark Office" *Tokai Corp. v. Easton Enterprises, Inc.*, 632 F.3d 1358, 1367 (Fed. Cir. 2011). For art that the PTO considered, Defendants "'ha[ve] the added burden of overcoming the deference that is due a qualified government agency presumed to have properly done its job.'" *Id.* (quoting *PowerOasis, Inc. v. T-Mobile USA, Inc.*, 522 F.3d 1299, 1304 (Fed. Cir. 2008)).

This provides an added reason to reject Defendants' obviousness argument. In allowing the '105 patent, the PTO considered five of the ten references Defendants rely upon (Nankai '420, Horii '998, Schulman '344, Yee '256, and Fujiwara '441). *See* Meyerhoff Supp. Decl., ¶ 130. Moreover, although the Examiner did not explicitly cite Winarta '229, he was aware of that patent and he cited the Winarta '451 patent on related technology, which was filed on the same day. The "added burden" discussed above also "extends to references" – such as Say '752 and Stewart '891 – "that are cumulative of those considered by the examiner." *Imports, LLC v. HJC I, LLC*, No. 2:11-CV-709 JCM, 2012 U.S. Dist. LEXIS 141727, at *5-6 (D. Nev. Oct. 1, 2012).⁵ The two remaining references (Khazanie and Lichten) are mathematics texts that discuss routine concepts known to those of skill in the art.

⁵ *See* Meyerhoff Supp. Decl., ¶¶ 131-35; *Elk Corp. v. GAF Building Materials Corp.*, 168 F.3d 28, 31 (Fed. Cir. 1999) ("[A]n otherwise material reference need not be disclosed if it is merely cumulative of ... other references already disclosed."); *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1178 (Fed. Cir. 1995) (same).

f. Secondary Considerations Confirm Claim 3's Nonobviousness

Secondary considerations must be addressed in any obviousness analysis. *Mintz v. Dietz & Watson, Inc.*, 679 F.3d 1372, 1379 (Fed. Cir. 2012). They are "often ... the most probative and cogent evidence of non-obviousness" *Star Scientific*, 655 F.3d at 1375 (citation omitted). Defendants ignore secondary considerations, and they provide strong evidence of nonobviousness.

Commercial success: OneTouch Ultra products used in practicing the method of the claimed invention have achieved enormous commercial success. LifeScan's OneTouch Ultra test strips [REDACTED]

[REDACTED] Meanwhile, LifeScan promotes the "DoubleSure Technology" on its packaging and in print and TV advertising, using its promotion of the patented technology to drive sales. *See* D.E. 176 at 4; D.E. 189, Exs. A-M. The high level of sales and the close nexus of those sales to the patented invention is strong evidence of nonobviousness. *Sciele Pharma, Inc. v. Lupin Ltd.*, 684 F.3d 1253, 1259 (Fed. Cir. 2012).

Copying: The GenStrip is a copy of the test strip disclosed in the '105 patent. *See* D.E. 176 at 5, 9; Meyerhoff Supp. Decl., ¶ 144. Defendants' copying of the claimed invention is further strong evidence of nonobviousness. *Ad. Display Sys. v. Kent State Univ.*, 212 F.3d 1272, 1285 (Fed. Cir. 2000); *Specialty Composites v. Cabot Corp.*, 845 F.2d 981, 991 (Fed. Cir. 1988).

2. The Claimed Invention Has Utility and Is Enabled

Defendants' remaining invalidity theory rehashes their untenable position that the '105 patent applies "incorrect science" when it recites "measuring an electric current at each working sensor part proportional to the concentration of [glucose] in the [blood]." D.E. 203 at 19, 33. As discussed above, Defendants' theory is at odds with the specification. "[T]he patent specification is written for a person of skill in the art, and such a person comes to the patent with the knowledge of what has come before." *LizardTech, Inc. v. Earth Resource Mapping, Inc.*, 424 F.3d 1336, 1345 (Fed. Cir. 2005). The '105 specification makes plain that the "proportional[ity]" recited in the claims was a feature of "[k]nown glucose measuring devices." D.E. 170-3 at col. 1:25-38. Because persons

1 skilled in the art could practice the prior art and measure the claimed proportionality without "undue
2 experimentation," there is no basis for Defendants' enablement and utility theory. *See In re Wands*,
3 858 F.2d 731, 740 (Fed. Cir. 1988); *see also* Meyerhoff Supp. Decl., ¶¶ 146-59.

4 **III. LifeScan Would Be Irreparably Harmed Absent an Injunction**

5 The facts on irreparable harm are largely undisputed. Defendants concede that:
6 (1) they are marketing GenStrip for use with LifeScan's meters; (2) GenStrip will be priced at half
7 the price of LifeScan's test strips, so that every \$1 of GenStrip sales translates into \$2 in lost
8 LifeScan sales; (3) Defendants expect GenStrip to take over 30% of LifeScan's sales in its first year
9 on the market; (4) this loss in sales would jeopardize LifeScan's market leadership position; (5) sales
10 of GenStrip would cause long-lasting erosion in LifeScan's prices; and (6) Defendants are small
11 companies without the funds needed to make LifeScan whole. These facts, and others, establish a
12 strong showing of irreparable harm. *See* D.E. 189 at ¶¶ 19, 22-26, 36-37; D.E. 176 at 16-21.

13 The most obvious irreparable harm is that Defendants will be unable to pay LifeScan
14 the money damages their infringement will cause. Defendants try to dismiss this concern in a
15 footnote. They do not dispute that their assets are too small to pay a judgment, but claim they will
16 make lots of money with infringing sales. D.E. 203 at 38 n.24. This self-serving argument was
17 rejected in *Robert Bosch LLC v. Pylon Manufacturing Corp.*, 659 F.3d 1142, 1154-55 (Fed. Cir.
18 2011). LifeScan's lost profits will *substantially* exceed any profits Defendants can realize by selling
19 GenStrip at half the price. And Defendants have not offered to escrow their infringement revenues
20 to pay back to LifeScan. LifeScan cannot be made whole by damages Defendants cannot pay.

21 The other harms to LifeScan are even more severe than previously anticipated. The
22 recent "fiscal cliff" legislation includes provisions on Medicare reimbursement that will result in

23 [REDACTED]

24 [REDACTED] But sales of GenStrip will
25 reduce LifeScan's sales and cause further price erosion beyond that caused by the fiscal cliff

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1 legislation. *See* Menziuso Supp. Decl., ¶¶ 16-16. These recent developments make the harm to
 2 LifeScan – and the threat to its viability as a business – particularly acute.

3 Defendants argue (D.E. 203 at 33-36) that LifeScan has not made "a sufficient
 4 showing of a causal nexus" between the infringement and sales of GenStrip. The language they cite
 5 from *Apple, Inc. v. Samsung Elecs. Co.*, 695 F.3d 1370, 1375 (Fed. Cir. 2012), is applicable to
 6 "cases such as [*Apple*] – where the accused product [a smartphone] includes many features of which
 7 only one (or a small minority) infringe." *Id.* at 1374. In such cases, *Apple* required a "strong causal
 8 nexus" between the harm and the infringement. *Id.*

9 This case does not present such issues. Unlike smartphones – which combine a
 10 phone with many unrelated patented features as diverse as a web browser, a camera, a navigator, a
 11 game launcher, and video and music players – GenStrip is designed to do only one thing: work with
 12 LifeScan's OneTouch Ultra meters as a substitute for OneTouch Ultra test strips to measure blood
 13 glucose levels. The very name GenStrip connotes a generic alternative to LifeScan's test strips, with
 14 all of the advantages, but at lower cost, than the patented product. Defendants promote GenStrip as
 15 providing "more accurate results," *see* www.shastagenstrip.com and www.pharmatechdirect.com, a
 16 claim that would not be possible without infringing the '105 invention and copying what LifeScan
 17 promotes as its DoubleSure technology. This is a sufficient showing of nexus under *Apple* (and the
 18 cases cited in our opening brief). In such circumstances, as the court held in *Bosch*, LifeScan's lost
 19 sales and market share, and Defendants' inability to pay, is irreparable harm. 659 F.3d at 1154-55.

20 **IV. The Balance of Equities and Public Interest Favor an Injunction**

21 Defendants devote only two paragraphs to the remaining factors. They argue that an
 22 injunction would be "catastrophic" for their business, D.E. 203 at 39, but "[o]ne who elects to build a
 23 business on a product found to infringe cannot be heard to complain if an injunction against
 24 continuing infringement destroys the business so elected." *Bosch*, 659 F.3d at 1156 (citation
 25 omitted). They also argue that an injunction would deny the public "a low cost alternative" to
 26

1 LifeScan's product, but "[s]elling a lower priced product does not justify infringing a patent." *Pfizer,*
2 *Inc. v. Teva Pharm., USA, Inc.*, 429 F.3d 1369, 1382 (Fed. Cir. 2005) (citation omitted).

3 Defendants' remaining argument, that LifeScan "waited" to seek a preliminary
4 injunction, D.E. 203 at 39, is defeated by their concession that LifeScan filed this motion "shortly
5 after the Court granted [LifeScan] to file the[] amended complaint" adding the '105 patent. *Id.* at 5.
6 LifeScan filed for a preliminary injunction as soon as it could – shortly after obtaining permission to
7 file its complaint and shortly after FDA approval made the risk of injury imminent.

8 **V. Conclusion**

9 For the reasons set forth above and in LifeScan's opening brief, this Court should
10 grant LifeScan's motion for a preliminary injunction.

11 Dated: February 15, 2013

Respectfully submitted,

12 /s/ Eugene M. Gelernter

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